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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/763,370 02/21/01 OGATA

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EXAMINER

HARRIS, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/763,370

Applicant(s)

Ogata et al.

Examiner
Alana M. Harris, Ph. D.

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 19, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-17 are pending.

Claims 3-6 and 12-16 have been amended.

Claims 1-17 are examined on the merits.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. The "...activity of osteoblasts..." and "...action of osteoclasts" recited in claims 1-6, 8 and 12-15 is vague and indefinite. It is not clear to one skilled in the art as to what activity or action to assess.

- b. Claim 1 is vague and indefinite for the recitation "A method of diagnosing bone metastasis of malignant tumor ...". It is not clear whether or not the tumor has metastasized from the bone to another organ or that the tumor has metastasized from an organ to the bone.

- c. The recitations "a marker associated with the phase of osteoblast proliferation", "...phase of calcification", "...phase of matrix maturation" in claims 2, 6, 12, 16 are vague and

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indefinite. Are there several phases of osteoblast proliferation, for example? Is the marker associated with only one particular phase? As written the claims suggest that there are several phases of osteoblast proliferation, calcification and matrix maturation.

d. Claims 3, 5, 7, 13, 15 and 17 recite several acronyms, for instance "PICP", "PINP", "BALP" and "ICTP". These acronyms should be fully spelled out.

e. The recitation "crossover index" in claims 6, 7, 16 and 17 is vague and indefinite. This term is not art known. The term should be clarified.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Plebani et al. (Clinical Biochemistry 29(1):67-72, February 1996). Plebani (see abstract and page 68, column 1, second full paragraph) discloses a method of diagnosing bone metastasis of malignant tumor using the following markers: carboxyterminal propeptide of type I procollagen (PICP), bone isoenzyme of alkaline phosphatase (ALP-B), osteocalcin (BGP), carboxyterminal telopeptide of type I collagen (ICTP) as well as known traditional markers. It is art known that PICP, ALP-B or

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BALP and BGP are bone formation markers associated with proliferation, matrix formation and mineralization or calcification. ICTP is a bone resorption marker.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
May 31, 2001


SHEELA HUFF
PRIMARY EXAMINER